IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

PAMELA BUTLER, et al.,	)	
	)	
Plaintiffs,	)	Case No. 4:18-cv-01701-AGF
v.	)	
	)	Lead Case
MALLINCKRODT LLC, et al.,	)	
	)	**ORAL ARGUMENT REQUESTED**
Defendants.	)	

DEFENDANTS' JOINT REPLY IN SUPPORT OF THEIR MOTION TO EXCLUDE THE TESTIMONY OF PLAINTIFFS' EXPERT JAMES CLARK, PH.D.

Defendants Mallinckrodt LLC ("Mallinckrodt") and Cotter Corporation (N.S.L.) ("Cotter") file this Reply in Support of Their Motion to Exclude the Testimony of Plaintiffs' Expert James Clark, Ph.D. (Doc. #49).

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Rules

I. INTRODUCTION

Defendant's motion and memorandum in support (Doc. #49 and #50) established, for several independent reasons, why Dr. Clark's opinions fail under Rule 702. Plaintiffs have the burden of establishing the admissibility of Dr. Clark's testimony and they have failed to carry that burden. Accordingly, and for the following specific reasons, the Court should exclude Dr. Clark's opinions under *Daubert* because:

- Plaintiffs cannot defend Dr. Clark's use of the Draft ATSDR Report because it is expressly prohibited by the report itself, and Plaintiffs instead misrepresent to the Court that the prohibition is not present in the Final Report—something that's just not true.

- Plaintiffs cannot defend Dr. Clark's justification for ignoring the ATSDR prohibition—that he "particularized" the data—because Defendants established Dr. Clark did not in fact do this to any degree and, in the one instance he attempted to do so, the attempt failed due to factual errors.

- Plaintiffs concede that Dr. Clark created his methodology in applying the Draft ATSDR Report for this litigation, that it has not been validated or subject to peer review, and that those who reviewed his work find he lacks "understanding of the basic tenets of radiation dosimetry."

- Plaintiffs, by their silence, concede that Dr. Clark manufactured his "background" levels of radiation, which contradict the levels universally agreed upon in the scientific community and the Price-Anderson Act case law.

- Plaintiffs do not refute that Dr. Clark's work is wrong 83% of the time and, contrary to Plaintiffs' argument, this error rate only counts errors in his *basic arithmetic*.

- Plaintiffs do not show that Dr. Clark produced the input data critical to his calculations, and thus Dr. Clark's analysis cannot be reproduced.

- Plaintiffs cite inapposite authority that considers novel relationships between toxins and disease; here, radiation is one of the most studied toxins in the world.

- Plaintiffs fail to explain Dr. Clark's "maximum" doses or provide any scientific authority that supports his methods for his alleged dose reconstruction.

- Plaintiffs produce no evidence showing that Dr. Clark is qualified to opine on radiation dose reconstructions in the first place.

II. STANDARD OF REVIEW

Plaintiffs do not dispute that they bear the burden of establishing the admissibility of Dr. Clark's testimony. *Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 757–58 (8th Cir. 2006). Plaintiffs wrongly portray the Eighth Circuit as an open door to unsupported testimony. In fact, the Eighth Circuit follows Supreme Court precedent that, under *Daubert*, the "district court's gatekeeping role separates expert opinion evidence based on 'good grounds' from subjective speculation that masquerades as scientific knowledge." *Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 989 (8th Cir. 2001). In other words, before admitting expert testimony, "the trial court must make 'a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.'" *Polski v. Quigley Corp.*, 538 F.3d 836, 838 (8th Cir. 2008) (quoting *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592–93 (1993)). Under this two-fold analysis, "[e]ven a theory that might meet certain *Daubert* factors, such as peer review and publication, testing, known or potential error rate, and general acceptance, should not be admitted if it does not apply to the specific facts of the case." *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1056 (8th Cir. 2000).

As Defendants' Memorandum details, Dr. Clark's opinion fails every single Rule 702 consideration: Dr. Clark has no scientific, technical, or other specialized knowledge that will help the trier of fact understand the evidence or determine a fact in issue, Rule 702(a); his opinion is not based on the facts or data in this case, Rule 702(b); his testimony is not the product of reliable principles or methods, Rule 702(c); and he fails to apply the principles and methods reliably to the facts of the case, Rule 702(d).

III. ARGUMENTS & AUTHORITIES

A. Dr. Clark Cannot Rely on the ATSDR Methodology to Survive Rule 702.

1. Dr. Clark Uses the ATSDR Methodology in a Manner It Prohibits.

Dr. Clark's entire methodology for calculating the individual Plaintiffs' doses rests on the Draft ATSDR Report. (Doc. #50 at 6–7.) As Plaintiffs admit, the Draft ATSDR Report states it cannot be used for such "detailed dose reconstruction." (Doc. #69 at 8.) Plaintiffs do not show the Court any authority to support Dr. Clark's use of the ATSDR in contravention of this prohibition and instead attempt to skirt it by telling this Court it was contained only in the *Draft* ATSDR Report and not the Final Report. (Doc. #69 at 8.) That is incorrect: the ATSDR's prohibition was also included manifold ways in the *Final* ATSDR Report, as detailed in Doc. #50 at 7–8.

This fact alone renders Dr. Clark's methodology unreliable. "When an expert relies on the studies of others, he must not exceed the limitations the authors themselves place on the study." *In re Accutane Prods. Liab.*, No. 8:04-MD-2523-T-30TBM, 2009 WL 2496444, at *2 (M.D. Fla. Aug. 11, 2009), *aff'd*, 378 F. App'x 929 (11th Cir. 2010). "Under *Daubert*, any step that renders the analysis unreliable . . . renders the expert's testimony inadmissible. This is true whether the step completely changes a reliable methodology or merely misapplies that methodology." *Goebel v. Denver and Rio Grande W. R. Co.*, 346 F.3d 987, 992 (10th Cir. 2003) (citations and internal quotations omitted). The decision in *Good v. Flour Daniel Corp.*, 222 F. Supp. 2d 1236, 1245 (E.D. Wash. 2002), is directly on point: Dr. Clark's methodology contradicts the basic principles of science by using the ATSDR Report in a manner it expressly prohibits.

2. Even If the Explicit Prohibition Did Not Exist, Dr. Clark's Use of the ATSDR Report Is Still Unreliable.

Putting the express prohibition aside, Plaintiffs attempt to defend Dr. Clark's use of the ATSDR Report by arguing its methodology was appropriate for ATSDR's own purposes. But

simply because the ATSDR Report may have been valid for its own purpose does not mean it is scientifically valid for Dr. Clark's purpose. *See In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 743 (3d Cir. 1994). "[T]he requirement of reliability, or 'good grounds,' extends to each step in an expert's analysis all the way through the step that connects the work of the expert to the particular case." *Id.* Plaintiffs do not cite a single authority that supports Dr. Clark's conversion of the ATSDR's draft methodology into an individual dose reconstruction, and it is Plaintiffs' burden to do so. *Marmo*, 457 F.3d at 757–58.

Courts routinely exclude experts for relying on public health assessments to support expert opinions in toxic tort cases. *See, e.g.*, *Nat'l Bank of Com. of El Dorado v. Associated Milk Producers, Inc.*, 191 F.3d 858, 860–61 (8th Cir. 1999); *Glastetter*, 252 F.3d at 991; *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1249–50 (11th Cir. 2005). This is because public health assessments are not individualized, are designed to overstate risk to meet their public protection mandate, and include thresholds for proof that are less stringent than those required to show causation in a tort context. Dr. Clark's testimony claimed to provide "dose-response calculations aim[ing] to identify the exposure levels that actually cause harm." *Williams v. Mosaic Fertilizer, LLC*, 889 F.3d 1239, 1247 (11th Cir. 2018). However, he was relying on methodology developed for "regulatory standards [that] often build in considerable cushion in order to account for the most sensitive members of the population and prophylactically protect the public." *Id.* As a result, the threshold of proof for regulatory agencies "is reasonably lower than that appropriate in tort law, which traditionally makes more particularized inquiries into cause and effect and requires a plaintiff to prove 'that it is more likely than not that another individual has caused his or her

harm.'" *Allen v. Pennsylvania Engineering Corp.*, 102 F.3d 194, 198 (5th Cir. 1996) (citing *Wright v. Willamette Industries, Inc.*, 91 F.3d 1105, 1107 (8th Cir. 1996)).[1]

Both the ATSDR Report itself and Plaintiffs' Opposition illustrate why the ATSDR methodology is not appropriate for an individual dose reconstruction. *First*, much like the cases above, the ATSDR confirmed it decided to overstate risk: "[O]ur methods are intended to obtain a conservative estimate of potential exposures using exposure point concentrations and other assumptions. The estimated exposures do not necessarily apply to individuals or even an average individual." (Doc. #50 at 7–8.) *Second*, as Plaintiffs note multiple times, the ATSDR designed its methodology to estimate "lifetime risks" and not individual doses at issue here (for exposures as little as 9 years for one of the Plaintiffs in this case). (Doc. #69 at 6, 8, 9.) This Court should follow the Eighth Circuit and sister circuits in rejecting expert opinions based on public health assessments. *See, e.g.*, *Glastetter*, 252 F.3d at 991; *Associated Milk Producers, Inc.*, 191 F.3d at 860–61; *McClain*, 401 F.3d at 1249–50.

3. Dr. Clark Admitted He Failed to "Particularize" the ATSDR Formulas.

Plaintiffs further attempt to justify Dr. Clark's use of the ATSDR methodology by arguing Dr. Clark "particularized" the numbers for Plaintiffs. This argument fails for three reasons. (*See* Doc. #50 at 12–13.) *First*, the ATSDR stated its *methodology* was inappropriate for individualized dose reconstructions altogether, which extends to Dr. Clark's purported particularization. *Second*, Dr. Clark admitted he failed to use accurate Plaintiff-specific information for his particularization (as discussed more fully below). *Third*, the only change Dr. Clark claims he made to the methodology in the Draft ATSDR Report was to attempt to change the years of exposure to match

[1] *See also Associated Milk Producers, Inc.*, 191 F.3d at 860–61 ("[R]egulatory agencies employ a different perspective in setting 'action levels' than do the courts in imposing tort liability. Establishing that the risk of causation 'is not zero' falls woefully short of the degree of proof required by *Daubert* and its progeny").

the years in which these Plaintiffs allege to have been exposed, but he admitted he used the wrong number for three of the four plaintiffs. (*Id*.)

4. Dr. Clark's Methodology Does Not Rely on the Facts of this Case.

Dr. Clark's testimony on this issue confirms his failures. His dose reconstruction methodology did not incorporate the Plaintiff-specific information he obtained in his interviews of Plaintiffs, the *Court-ordered* questionnaires designed to elicit exposure information, or the Plaintiffs' deposition testimony regarding the actual time Plaintiffs allege they were exposed at Coldwater Creek. (Doc. #50 at 11-15.) Rather than use Plaintiff-specific information, or in other words, the actual facts of the case, Dr. Clark adopted the ATSDR's hypothetical estimates to "calculate" the daily radiation intake each Plaintiff experienced from Coldwater Creek. *Id*.

Significantly, the Plaintiffs' actual information was available to Dr. Clark; he just chose not to use it. (*Id*.) Plaintiffs assert this failure is a non-issue because "the total time each Plaintiff spent at contaminated areas and activities they engaged in there are questions of fact for the jury." (Doc. #69 at 13.) Not true. *First*, the jury will not be asked to determine how long these Plaintiffs were exposed to Coldwater Creek and to reconstruct a dose from that information. That was Dr. Clark's task and he failed to perform it reliably. *Second*, even if a jury were to decide the total time each Plaintiff was exposed to alleged radiation from Coldwater Creek, it would have no bearing on Dr. Clark's opinion. As he confessed, he did not incorporate the time the Plaintiffs testified to actually spending at Coldwater Creek into his methodology; he just adopted whatever hypothetical numbers the ATSDR generated. (Doc. #50 at 12.) Regardless of what a jury may believe, Dr. Clark's opinions are fundamentally unsound and unreliable right now and under Supreme Court precedent must be excluded now.

Dr. Clark's decision to ignore the evidence in this case requires exclusion under *Daubert*. *See Concord Boat Corp.*, 207 F.3d at 1057. The authority Plaintiffs cite for their contrary position

does not help their argument: *Synergetics, Inc. v. Hurst*, 477 F.3d 949, 955 (8th Cir. 2007), addresses when parties merely disagree about competing, yet reliable assumptions. Here, in contrast, the undisputed record evidence—by Dr. Clark's own concession—is that Dr. Clark used exposure time periods that did not account for the specific information Plaintiffs provided about their exposure time. (Doc #50 at 12, citing Doc. #50-2, Clark *Butler* 192:13–19.) Thus, his opinions do not "fit" any Plaintiff in this case. In an attempt to explain away his failure, Dr. Clark contends Plaintiffs' deposition testimony was not reliable because *sworn deposition testimony is not reliable.* (Doc. #69 at 13). But neither Dr. Clark nor Plaintiffs provide any authority supporting this novel theory. Rather, Plaintiffs' own authority recognizes that in exercising its gatekeeping function under *Daubert*, the trial court must assess whether the methodology is scientifically valid *and* whether that methodology can be properly and relevantly applied to the facts in issue. *Synergetics*, 477 F.3d. at 955. If a method is divorced from the actual facts of the case, as is the case here, it is not reliable. *Concord Boat Corp.*, 207 F.3d at 1057.

5. Despite Relying Exclusively on the ATSDR, Dr. Clark Did Not Reliably Apply It.

Not only is Dr. Clark's use of the ATSDR Report for his purpose prohibited, but he did not even use the conclusions from the Final ATSDR Report. He relied exclusively on the *Draft* ATSDR Report. He never even read the *Final* ATSDR Report. Therefore, he did not correct the errors ATSDR made in the Draft ATSDR Report, which it acknowledged and corrected in the Final ATSDR Report. The ATSDR reduced all of its estimated doses from the Draft ATSDR Report to the Final, and it also reduced the bone cancer coefficient Dr. Clark incorporated into *all* of his dose reconstructions. (Doc. #50 at 10–11). The ATSDR's latter correction lowered its calculations by a factor of ten. (*Id.* at 11) Dr. Clark did not make either of these corrections and his calculations are therefore all inflated by a factor of ten. (Clark *Butler* 125:9–17.)

Plaintiffs suggest this error is harmless because the ATSDR stated the change did not affect the ATSDR's overall conclusions. (Doc. #69 at 10–11.) But this contention has two problems. *First*, as Plaintiffs admit, the ATSDR revised its work to correct for this error and then, only after reviewing the revised results, determined *from a public health perspective* that the correction did not affect the ATSDR's conclusions. (Doc. #69 at 10–11.) Dr. Clark has never corrected for this error, so he cannot show what the actual effect of this correction would have on the individualized doses he calculated for Plaintiffs or on his conclusions. (Doc. #50 at 10; Clark *Butler* 125:9–17.)

Second, even though they rely on the ATSDR's methodology, Plaintiffs and Dr. Clark do not agree with the ATSDR's conclusions. Despite all of the conservative assumptions the ATSDR made to overstate exposure, the ATSDR concluded there was not even an elevated *risk* of cancer for the cancers here (breast, brain, and mantle cell lymphoma). Plaintiffs cannot genuinely argue that Dr. Clark's error-riddled reliance on an uncorrected draft report is excusable because ATSDR did not change its ultimate conclusion that there is no risk of cancer for these cancers while simultaneously arguing that ATSDR's conclusion is wrong. Further, Plaintiffs' argument that these errors are insignificant because the range of doses Dr. Clark incorporates into his calculations are within the range of doses produced in the ATSDR's Health Assessment and the USEPA Baseline Risk Assessment suffers from the same flaw as his reliance on public health assessments, discussed above in Section III.A.2.

6. Dr. Clark Did Not Know What PEF He Included in His Work and Discovered at His Deposition That It Derives from an Activity That None of These Plaintiffs Did.

Because Dr. Clark relied exclusively on the Draft ATSDR Methodology, Dr. Clark incorporated the ATSDR's Particulate Emission Factor ("PEF") into his work.[2] The ATSDR's

[2] For a detailed explanation of the PEF, see Doc. #50 at 14.

PEF derives from the amount of dust particles the rider of an ATV would inhale if the individual were on the second of two ATVs traveling single-file on trails in Colorado. The ATSDR then applied this elevated PEF to every single activity it analyzed as a possible avenue for exposure (e.g., walking, gardening, playing by the creek). (*See* Doc. #50 at 14–15.)

Dr. Clark did not know what the PEF value in his work was based upon. (*Id*.) Thus, he could not have relied upon it in a scientifically sound manner. (Clark *Butler* 143:5–9.) He also admitted there was no evidence of any Plaintiff riding an ATV near Coldwater Creek, much less one breathing the dust from an ATV in front of them, as well. (Clark *Butler* 143:20–144:5.)

Plaintiffs urge the Court to ignore this error because the ATSDR concluded that use of this emission factor reflects its conservative public health assessment. (Doc. #69 at 13.) This simply makes Defendants' point, emphasized in the cases cited above and the Draft ATSDR Report itself: a public health assessment cannot be used for individualized dose reconstruction because it serves an entirely different purpose.

B. Dr. Clark's Use of the ATSDR Methodology for an Independent Dose Reconstruction Was Made for This Litigation, Was Not Validated or Subject to Peer Review, and Those Who Have Reviewed His Work Find It Lacking.

Plaintiffs do not dispute that Dr. Clark created his methodology solely for litigating this matter. (Doc. #69 at 9–10.) *See Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 157 (1999) (expert properly excluded when there was no evidence methodology was used by other experts in industry and no supporting literature). Nor do they dispute that his current methodology is his third attempt at an unreliable methodology for calculating radiation exposures after his failed attempts at using the RESRAD and GENII models. (Doc. #69 at 9–10.) Rather than point to case law or scientific authorities that support Dr. Clark's methodology, Plaintiffs take a shot at the creator of GENII, Bruce Napier, by arguing Defendants paid Mr. Napier to write an affidavit that described how Dr. Clark had no idea what he was doing with regard to dose reconstruction and the GENII

model. (Doc. #69 at 9.) Even this tangential argument is not true. Mr. Napier created the GENII model, reviewed Dr. Clark's use of it *without compensation*, and concluded that Dr. Clark's misuse of the model showed a "distinct lack of understanding of the basic tenets of radiation dosimetry as applied since the 1980s." (Doc. #50, Ex. 7 at 3, 8.)

Dr. Clark's method of relying on the Draft ATSDR Report for individual dose reconstruction and the error-riddled calculations that flow from it have never been objectively or independently validated, and the method is therefore scientifically unsound. (Clark *Butler* 141:16–9.) Also, it has never been approved through peer-review. (Clark *Butler* 96:22–98:9; Clark *Czapla* 240:7–10.) In fact, the closest his methodology has come to peer review is the ATSDR's admonition that the methodology should *not* be used for individual dose reconstruction. Dr. Clark's applied methodology exemplifies made-for-litigation "science" that must be excluded. *See Daubert*, 509 U.S. at 593–94; Fed. R. Evid. 702 advisory committee's notes.

C. Plaintiffs Did Not Address Dr. Clark's Use of a Fictional Background Number That Is Contradicted by the Sources He Relied on, Case Law and All Other Authoritative Sources.

Dr. Clark conjured up a background number in this case to which he could compare his otherwise erroneous doses, thus giving the appearance of significance to his and Dr. Hu's opinions. (Doc. #50 at 17–18.) Plaintiffs make no effort to establish the admissibility of Dr. Clark's fictional background number, and in fact, do not address this issue at all.

Ionizing radiation is a unique toxin in the sense that everyone is exposed to it at all times. (*Id.*) As a result, scientific authorities and case law recognize the need to distinguish an exposure from background in order for it to be significant. (*Id.*) Dr. Clark understood this principal because he presented his doses in terms of their comparison to a background level, but he failed to use the universally accepted natural background level set forth in the ATSDR Report, every other authoritative source, and every case cited to the Court that addresses background.

Dr. Clark's choice to use his own made-up background level, rather than the universally accepted natural background, is not reliable. This failure, like all of Dr. Clark's failures, is replicated in Dr. Hu's causation opinions because Dr. Hu simply adopted wholesale Dr. Clark's error-riddled and scientifically invalid opinions to render his own opinions. (Doc. #52, at 13–16.)

D. Dr. Clark Performed 83% of His Calculations Wrong.

As Defendants explain, Dr. Clark performed 83% of his calculations wrong. (Doc. #50 at 14–15.) While Plaintiffs admit that Dr. Clark's work is replete with errors (Doc. #69 at 14–15), they urge the Court to find his staggering error rate irrelevant. (Doc. #69 at 14.)

First, Plaintiffs are wrong when they contend the error rate incorporates issues beyond basic math. The 83% error rate was generated directly and solely from arithmetic mistakes Dr. Clark made in calculating his doses. (Defs,' Mem. 15–16.) Certainly, this volume of mathematical errors renders his opinions meaningless and unreliable under Rule 702. *See Daubert*, 509 U.S. at 593–94; Fed. R. Evid. 702 advisory committee's notes.

Second, the only cases the Plaintiffs could muster to defend Dr. Clark's errors are inapposite as they deal with spectrographic voice identification methods that have since been ruled unreliable. (Doc. #69 at 15 (citing *United States v. Smith*, 869 F.2d 348, 353–54 (7th Cir. 1989)).) In *Smith*, the Seventh Circuit applied the *Frye* test—now superseded by Rule 702 as stated in *Daubert*. Since *Daubert*, other circuits have affirmed the exclusion of spectrographic evidence as failing Rule 702. *See, e.g., United States v. Salimonu*, 182 F.3d 63, 73 (1st Cir. 1999); *United States v. Mills*, 858 F. App'x 463 (3d Cir. 2021). That is because, while "the technology has improved," it is now "not generally accepted by the scientific community." *Mills*, 858 F. App'x 463. Indeed, since 2003, "no federal court has accepted such voice identification evidence." *Id.*

Plaintiffs cannot avoid the fact that Dr. Clark's high error rate alone requires exclusion. *See Daubert*, 509 U.S. at 593–94; Fed. R. Evid. 702 advisory committee's notes.

E. Dr. Clark's Calculations Cannot Be Reproduced.

Dr. Clark's analysis cannot be reproduced. Plaintiffs try to confuse this issue by stating it would be impossible for Defendants to know Dr. Clark's error rate and at the same time profess they cannot replicate his work. Plaintiffs misunderstand the nature and multiple levels of Dr. Clark's errors. His embarrassing error rate comes from the errors in simple math calculations he produced to support his work. In contrast, Defendants' inability to reproduce Dr. Clark's work relates not to these basic math errors but to his use of a program called ProUCL. (Clark *Butler* 77:1–6.) The ProUCL program takes certain input information and provides output information for a foundation to perform a dose reconstruction. Dr. Clark testified to his *input* information during his deposition, and after his deposition he produced printouts of the input data he claims to have used. (Doc. #50 at 16–17.) But the information he provided did not support his *outputs*, and Dr. Clark was never able to produce the data that he would have used to produce his doses. *Id*.

F. Missouri and Eighth Circuit Law Do Not Allow Experts to Testify to Causation If Their Opinions Are Not Reliable.

Plaintiffs argue that Missouri and Eighth Circuit law would allow Dr. Clark to testify to exposures beyond what he opined in his report, but that is not the law. (Doc. #69 at 18–19.) And that is not what Dr. Clark testified to, nor is it the subject of this motion. Dr. Clark testified to specific doses of radiation, and he compared those doses to a fictional background. His methodology on those opinions is unreliable and should be excluded.

Plaintiffs obviously want Dr. Clark to testify to exposures beyond the doses he calculated because they know his doses are unreliable and insignificant, but the cases they cite do not stand for this proposition. Both *Bonner v. ISP Technologies, Inc.*, 259 F.3d 924 (8th Cir. 2001), and *Kirk v. Schaeffler Group USA, Inc.*, 887 F.3d 376 (8th Cir. 2018), consider novel relationships between toxins and disease, and the experts testified to the limitations in their work based on the novel

nature of it. (Doc. #69 at 18; *Bonner*, 259 F.3d at 928; *Kirk*, 887 F.3d at 390–91.) As Plaintiffs note, the experts in *Kirk* "could not give any level of [Plaintiffs'] exposure." (Doc. #69 at 20 *citing* 887 F.3d at 390–91). Here, Dr. Clark did not testify to, and Plaintiffs do not argue, that radiation is a novel toxin or that doses could not be developed for these Plaintiffs. The evidence shows the opposite. Radiation is one of the most studied toxins in the world and Dr. Clark tried, but failed, to develop reliable doses for these Plaintiffs.

G. Dr. Clark's Use of the "Reasonable Maximum Exposure" and "Maximum" Exposure Is Not Reliable.

Plaintiffs mischaracterize Defendants' arguments regarding Dr. Clark's use of the Reasonable Maximum Exposure ("RME") and his separate calculation of Plaintiffs' "Maximum" doses. Plaintiffs assert Dr. Clark's use of these "exposure doses" is appropriate because the ATSDR and EPA use these types of calculations for public health assessments and regulatory purposes, but Plaintiffs do not cite *a single piece of evidence or authority* that shows these doses are appropriate for the dose reconstruction needed for this tort litigation. As explained above, ATSDR/EPA have a different purpose for their work than Dr. Clark. (*See supra* § III.A.2.)

Stated more specifically, Dr. Clark described his RME dose as the "highest exposure that is reasonably expected to occur at a site" and as "well above the average." (Clark *Butler* 82:1–84:3.) Yet he does not explain why this estimate is an appropriate dose for analyzing Plaintiffs' exposures. Coupled with his inability to point to a scientific authority that supports these methods for an independent dose reconstruction, this is precisely why his opinions should be excluded. *Cano v. Everest Minerals Corp.*, 362 F. Supp. 2d 814 (W.D. Tex. 2005), is directly on point. (*See* Doc. #50 at 19.) The expert in *Cano* tried to inflate the plaintiffs' doses—much like Dr. Clark does here—and his testimony was rightly excluded. *Id*. at 858. So, too, should Dr. Clark's testimony be excluded.

Dr. Clark's "Maximum" doses (up to 300 times more than the Reasonable Maximum Exposure based doses Dr. Clark originally calculated) fail for even more reasons. Plaintiffs argue that Dr. Clark's Maximums are appropriate because the Plaintiffs could have moved around during any given day and thus could be exposed to radiation at several locations a day. (Opp. at 23.) But that is not how Dr. Clark calculated his Maximums. He calculated his Maximums by assuming each Plaintiff was *simultaneously* located in different locations—where each of the three different radionuclides at issue were at their highest levels. (Doc. #50 at 20–21.) Dr. Clark then assumed the Plaintiffs were simultaneously exposed at all of those different locations for their entire exposure history. (*Id.*) This would require each Plaintiff to be in multiple locations at the same time for the entire time they were exposed to radiation. This premise is obviously impossible, and the resulting dose cannot be possible, as even Dr. Hu admits. (Doc. #50 at 14.)

H. Dr. Clark Failed at Every Step of His Analysis and in Doing So Confirmed What His Lack of Education, Experience, or Training Reveals; He Is Not Qualified to Opine on Radiation Dose Reconstructions.

Dr. Clark did not perform a proper individual dose reconstruction by any stretch of the imagination. He took the methodology from the *Draft* ATSDR Report, used it for a purpose prohibited by the report itself, incorrectly incorporated the years he believed the Plaintiffs were exposed to Coldwater Creek, and invented doses that have no relationship to reality. He did not even utilize the exposure information the Court ordered all Plaintiffs to provide for use in this litigation. When he tried to calculate doses using this improper methodology, his math calculations were wrong *83%* of the time. And then he compared his doses against a made-up background number contradicted by science and law.

Dr. Clark's failures, each of which is significant enough to warrant exclusion, illustrate the final reason Dr. Clark's opinions fail *Daubert*—he is simply not qualified to render radiation dose reconstruction opinions. Dr. Clark has no education, background, or training in radiation science.

(Doc. #50 at 22–23.) He is not a health physicist, radiation biologist, radiation dosimetrist, or mathematical modeler. (*Id*.) He is not a member of any professional societies specific to radiation. (*Id*.) He has never served on a national or international scientific committee related to radiation or any other relevant discipline. (*Id*.) He has never published any articles related to radiation exposure or radionuclides in the environment. (*Id*.) He admits he has taken no coursework in the relevant topics of radiation dosimetry, nuclear physics, or nuclear engineering. (*Id*.) Before the *McClurg* litigation, Dr. Clark had never calculated a radiation dose. (*Id*.) He simply claimed to be "self-taught" on the models he has tried to use in this litigation, and it shows. (*Id*.)

Instead of refuting these admissions, Plaintiffs respond that Dr. Clark is a toxicologist, exposure analyst, and air modeler. But Plaintiffs do not offer any support for how this qualifies Dr. Clark to render a radiation dose reconstruction opinion, a subject matter he admits he has never studied. Likewise, he may in fact be an air modeler, but he did not create an air model here. Quite simply, he has no training, education, or experience that qualifies him to perform the work he has attempted in these cases. Finally, Defendants established Dr. Clark was not qualified to opine on cancer risk based on his admissions, a point Plaintiffs impliedly concede through silence. (Doc. #50 at 24–25.) The Eighth Circuit has "repeatedly upheld the exclusion or reversed the admission of expert design testimony that went beyond the expert's expertise." *Am. Auto. Ins. Co. v. Omega Flex, Inc.*, 783 F.3d 720, 724 (8th Cir. 2015) (collecting cases); *Smith v. Rasmussen*, 249 F.3d 755, 759 (8th Cir. 2001) (collecting different cases). Here, Dr. Clark fails that threshold step as to his opinions both on radiation dosimetry and the Plaintiffs' increased cancer risk.

IV. CONCLUSION

For these reasons, Defendants request that this Court enter an Order excluding Dr. Clark's testimony because it does not meet the requirements for admissibility under Federal Rule of Evidence 702 and *Daubert*.

Dated: October 22, 2021

Respectfully submitted,

/s/ David R. Erickson
David R. Erickson, #31532MO
Steven D. Soden, #41917MO
Anthony R. Martinez, #61791MO
Poston E. Pritchett, #72303MO
SHOOK, HARDY & BACON LLP
2555 Grand Boulevard
Kansas City, Missouri 64108-2613
Telephone: 816.474.6550
Facsimile: 816.421.5547
derickson@shb.com
ssoden@shb.com
amartinez@shb.com

ATTORNEYS FOR DEFENDANT
MALLINCKRODT LLC

/s/ Brian O. Watson
Brian O. Watson, #68678MO
Jennifer Steeve, #308082CA
Lauren E. Jaffe, #6316795IL
RILEY SAFER HOLMES & CANCILA LLP
70 W. Madison St., Ste. 2900
Chicago, Illinois 60602
(312) 471-8700 (main)
(312) 471-8701 (fax)
ecasmere@rshc-law.com
bwatson@rshc-law.com
jsteeve@rshc-law.com
ljaffe@rshc-law.com

ATTORNEYS FOR DEFENDANT
COTTER CORPORATION (N.S.L.)

CERTIFICATE OF SERVICE

I hereby certify that on the 22nd day of October 2021, I served the above to the following counsel of record via the Court's electronic filing system.

Kenneth B. McClain #32430
kbm@hfmlegal.com
Jonathan M. Soper #61204
jms@hfmlegal.com
Colin W. McClain #64012
cwm@hfmlegal.com
221 W. Lexington, Suite 400
P.O. Box 900
Independence, Missouri 64050
(816) 836-5050
(816) 836-8966 FAX

ATTORNEYS FOR PLAINTIFFS

Brian O. Watson, #68678MO
Jennifer Steeve, #308082CA
Lauren E. Jaffe, #6316795IL
RILEY SAFER HOLMES & CANCILA LLP
70 W. Madison St., Ste.
2900
Chicago, Illinois 60602
(312) 471-8700 (main)
(312) 471-8701 (fax)
ecasmere@rshc-law.com
bwatson@rshc-law.com
jsteeve@rshc-law.com
ljaffe@rshc-law.com

ATTORNEYS FOR DEFENDANT
COTTER CORP. (N.S.L.)

/s/ *David R. Erickson*
David R. Erickson, #31532MO
Steven D. Soden, #41917MO
Jason M. Zager, #59432MO
Anthony R. Martinez, #61791MO
Poston E. Pritchett, #72303MO
SHOOK, HARDY & BACON LLP
2555 Grand Boulevard
Kansas City, Missouri 64108-2613
Telephone: 816.474.6550
Facsimile: 816.421.5547
derickson@shb.com
ssoden@shb.com
jzager@shb.com
amartinez@shb.com
ppritchett@shb.com

ATTORNEYS FOR DEFENDANT
MALLINCKRODT LLC